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| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|----------------------------|---------------|-----------|-----------------------|--------------------------|------------------|--|
| 10/578,953 | 05/10/2006 | | Philippe G. Nantermet | 21585YP | 5003 | |
| ²¹⁰ MERCK AN | | 5/26/2007 | • | EXAMINER . | | |
| P O BOX 2000 | | | | DAVIS, ZINNA NORTHINGTON | | |
| RAHWAY, I | NJ 07065-0907 | | • | ART UNIT | PAPER NUMBER | |
| | | | 8 | 1625 | | |
| | | | | MAIL DATE | DELIVERY MODE | |
| | | | | 06/26/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | Application No | • | Applicant(s) | | | | |
|---|---|---------------------------|------|------------------------|--|--|--|--|
| | | 10/578,953 | | NANTERMET ET AL. | | | | |
| | Office Action Summary | Examiner | - | Art Unit | | | | |
| | | Zinna Northingto | | 1625 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | | |
| Status 1)∐ | Responsive to communication(s) filed on | • | | | | | | |
| | | — · is action is non-l | inal | | | | | |
| 3) | , | | | | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims | | | | | | | | |
| 4) Claim(s) 1-19 is/are pending in the application. | | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | | | |
| 7) | Claim(s) is/are objected to. | | | | | | | |
| 8) Claim(s) 1-19 are subject to restriction and/or election requirement. | | | | | | | | |
| Application Papers | | | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | | |
| 10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner. | | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | |
| 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. | | | | | | | | |
| If approved, corrected drawings are required in reply to this Office action. | | | | | | | | |
| 12)☐ The oath or declaration is objected to by the Examiner. | | | | | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | | | |
| a)L | ☐ All b)☐ Some * c)☐ None of: | | | | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| 14)⊠ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). | | | | | | | | |
| a) The translation of the foreign language provisional application has been received. | | | | | | | | |
| 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. Attachment(s) | | | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s) | | | | | | | | |
| 2) Notice | of Draftsperson's Patent Drawing Review (PTO-948) lation Disclosure Statement(s) (PTO-1449) Paper No(s) | 5) | | Patent Application (PT | | | | |

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1. Claims 1-19 are pending.

2. Upon thorough consideration of the claims, the examiner believes that a lack of

unity of invention exists, as defined in Rule 13.

3. PCT Rule 13.1 states that the international application shall relate to one

invention only or to a group of inventions so linked as to form a single general inventive

concept ("requirement of unity of invention").

PCT Rule 13.2 states that unity of invention referred to in Rule 13.1 shall be

fulfilled only when there is a technical relationship among those inventions involving one

or more of the same or corresponding special technical features.

Annex B, Part 1(a), indicates that the application should relate to only one

invention, or if there is more than one invention, inclusion is permitted if they are so

linked to form a single general inventive concept.

Annex B, Part 1(b), indicates that "special technical features" means those

technical features which as a whole define a contribution over the prior art.

Annex B, Part 1(c), further defines independent and dependent claims. Unity of

invention only is concerned in relation to independent claims. Dependent claims are

defined as a claim which contains all the features of another claim and is in the same

category as the other claim. The category of a claim refers to the classification of

claims according to subject matter, e.g. product, process, use, apparatus, means, etc.

Annex B, Part 1(e), indicates the permissible combinations of different categories of

claims. Part 1(e(l)) states that inclusion of an independent claim for a given product, an

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independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product is permissible.

Annex B, Part 1(f) indicates the "Markush practice" of alternatives in a single claim. Part 1(f(I)) indicates the technical interrelationship and the same or corresponding special technical feature is considered to be met when: (A) all alternatives have a common property or activity, and (B) a common structure is present or all alternatives belong to a recognized class of chemical compounds. Further defining (B) in Annex B, Part 1(f)(I-iii), the common structure must; a) occupy a large portion of their structure, or b) the common structure constitutes a structurally distinctive portion, or c) where the structures are equivalent and therefore a recognized class of chemical compounds, each member could be substituted for one another with the same intended result. That is, with a common or equivalent structure, there is an expectation from knowledge in the art that all members will behave in the same way. Thus, the technical relationship and the corresponding special technical feature result from a common (or equivalent) structure which is responsible for the common activity (or property). Part 1(f(iv)) indicates that when all alternatives of a Markush grouping can be differently classified, it shall not, taken alone, be considered justification for finding a lack of unity. Part 1(f(v)) indicates that when dealing with alternatives, it can be shown that at least one Markush alternative is not novel over the prior art, the question of unity of invention shall be reconsidered, but does not imply that an objection shall be raised.

4. Restriction is required under 35 U.S.C. 121 and 372.

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This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, drawn to a chemical compound of formula (I) and a pharmaceutical composition.

Group II, claim(s) 18, drawn to a method for inhibition of β -secretase activity in a mammal using a chemical compound of formula (I).

Group III, claim(s) 19, drawn to a method for treating Alzheimer's disease in a patient using a chemical compound of formula (I).

5. The application does not meet the requirement for Unity of Invention for the following reasons: 1) the permissible combinations under Annex B, Part 1(e) are lacking and 2) a common structure is not present under Annex B, Part 1(f) in which the utility is attributed. See the radicals as defined by formula I such as A, X, Y, R¹, R², and R³

Therefore, a lack of unity of invention exists.

- 6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.
- 7. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

- 8. Due to the complexity of the lack of unity, a written request is made.
- 9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).
- 10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna N. Davis whose telephone number is 571-272-0682. The examiner can normally be reached on M-F.
- 12. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
- 13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zinna Northington Davis
Primary Examiner
Art Unit 1625

Znd June 20, 2007